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| 10/821,718 | 04/09/2004 | Clyde L. Schultz | RH01.701US | 1509 |

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Finch & Maloney PLLC
175 Canal Street
Suite 503
Manchester, NH 03101

| EXAMINER | |
|---|---|
| ALAWADI, SARAH | |
| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/821,718 | SCHULTZ, CLYDE L. | |
| | Examiner | Art Unit | |
| | SARAH AL-AWADI | 1619 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-19 and 21-25* is/are pending in the application.

4a) Of the above claim(s) *15-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 21-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/31/2010 and 04/17/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Receipt of Applicants amendments/remarks filed on 03/30/2010 is acknowledged. The Examiner acknowledges the following:

Currently claim 1 and claim 22 have been amended to recite a specific tetrapolymer hydrogel.

Claims 1-14 and 21-25 are under Examination.

Two Declarations under 37 CFR 1.132 have been filed on 03/30/2010.

## INFORMATION DISCLOSURE STATEMENT

The Examiner acknowledges the IDS received on 03/30/2010 and 04/16/2010.

## WITHDRAWN REJECTIONS

Double Patenting

Claims 1-14, 21-23 and 25 are rejected on the grounds of non-statutory double patenting over US Patent 7,169,406. Applicants have filed a Terminal Disclaimer which has been approved therefore the rejection is hereby **withdrawn.**

Claims 1-14 are rejected on the grounds of non-statutory double patenting over US Patent Application No. 11/102,454. Applicants have filed a Terminal Disclaimer which has been approved therefore the rejection is hereby **withdrawn.**

Rejection under 112 1st Paragraph

Claims 22-23 are rejected under 35 U.S.C. 112 1st paragraph as failing to comply with the written description requirement for the term VEGF antagonist. In view of Applicants arguments and presentation of new journal articles demonstrating VEGF antagonists, the rejection is hereby **withdrawn.**

Rejection under 35 USC 102(b)

Claims 1, 6-13 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Guy Fortier, US Patent No. 5,733,563. In light of Applicant's amendment to claim 1, namely the addition of a specific tetrapolymer, said rejection is hereby **withdrawn.**

Claims 1,6-13 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Rajan Bawa, US Patent No. 4,668,506. In light of Applicant's amendment to claim 1, namely the addition of a specific tetrapolymer, said rejection is hereby **withdrawn**

Rejection under 35 USC 103(a)

Claims 1, 2-3, 5-14, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz United States Patent Application 2002/0197300 and Schwartz, United States Patent 5,212,168. In light of Applicants amendment to claim 1 said rejections are **withdrawn.**

Claims 1-3,6-13 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. United States Patent Application 2004/007176 in view of Wikipedia (hydrogel article). In light of Applicants amendments, most notably to claims 1 and 22, said rejection is herby **withdrawn.**

Claims 22-25 stand rejected under 35 U.S.C. 103(a) over Sponsel, US Patent Application No. 2004/0198829. In light of Applicants amendments, most notably to claims 1 and 22, said rejection is herby **withdrawn.**

## MAINTAINED REJECTIONS

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14, 21-23 and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending **Application No. 10/971,997.** Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed toward a polymeric hydrogel comprising a drug such as a steroid wherein the drug is capable of treating posterior segment disease. The

drug can be a number of agents such as steroids and VEGF antagonists. The hydrogel has a water content of between 10% and 90% or between 37.5% and 75% and is composed of a tetrapolymer of hydroxymethylmethacrylate, ethylene glycol, dimethacrylate, and methacrylic acid. The hydrogel can be a contact lens capable of correcting vision in the range of +8.0 to -8.0 diopters and has a base curve of 8.0 and 9.0. The drug is further capable of being passively delivered to the posterior segment of the eye or ocular environment.

The '997 claims are similar in that the treatment consists of an anti-angiogenesis compound. Furthermore, instant claim 20 specifically states the drug can be an angiogenesis inhibitor and VEGF antagonist. Additionally, tamoxifen, thalidomide and VEGF antibodies are stated as the drugs in both applications. The '997 also discloses steroid molecules such as tetrahydrocortisol-S as the types of drugs used with the hydrogel.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to make a polymeric hydrogel for the treatment of posterior segment disease because '997 teaches the use of the same hydrogel and the same drugs.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

## NEW REJECTIONS

In view of Applicants amendment to claims 1 and 22, with the addition of the tetrapolymer, the following rejections are newly applied:

### *Claim Objections*

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case claim 5 recites the identical tetrapolymer of newly amended claim 1, therefore it does not limit the hydrogel of claim 1.

***Claim Rejections - 35 USC § 103***

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. United States Patent Application 2002/0197300 and Schwartz, United States Patent 5,212,168.

Schultz et al. teaches polymeric hydrogel contact lenses wherein the lenses gradually release medication. (abstract and paragraph 0014) Schultz et al. teaches a tetrapolymer hydrogel such as hydroxymethylmethacrylate, ethylene glycol, dimethylmethacrylate, and methacrylic acid. (paragraph 0020) The limitation wherein the hydrogel comprises a drug for the "treatment

of a posterior segment disease is interpreted by the Examiner as an intended use of the composition. MPEP 2111.02 recites "if a prior art structure is capable of performing the intended use as recited then it meets the claim." Schultz et al. expressly teaches the use of hydrogels to release drugs to the eye. Schultz further teaches that it is known to deliver such anti-glaucomatous medications in combination with corticosteroid medications and discloses U.S. Patent 5,212,168 which exemplifies that using polymeric hydrogel contact lenses to deliver anti-glaucomatous medications in combination with corticosteroid medications is well known in the art. The corticosteroid medications of U.S. Patent 5,212,168 include that of prednisolone, prednisone, and hydrocortisone which can be delivered through a polymeric hydrogel. Regarding the limitations wherein the drug is used for the treatment of a posterior segment disease, the Examiner interprets said limitation as reciting an intended use, see above. Regarding the limitation wherein the drug is capable of being passively released from the polymeric hydrogel while positioned on the eye in a therapeutically effective amount to ameliorate and/or stabilize neovascularization in the posterior segment; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner as a property and is directed toward the polymeric hydrogel which is instantly claimed.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to form polymeric hydrogels as taught by Schultz et al., wherein such hydrogels comprise steroids to ameliorate and/or stabilize neovascularization because Schultz et al. suggests that it is known in the art to incorporate corticosteroids into such hydrogels. There would have been a reasonable expectation of success as Schultz et al. teach the use of hydrogels to deliver drugs to the eye.

Claims 2-3, 6-14, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. United States Patent Application 2002/0197300 with respect to claim 1 as presented above.

Claim 3 recites the polymeric hydrogel of claim 1, wherein the hydrogel has a water content of between 10% and 90%, and claim 3 recites the polymeric hydrogel of claim 2, wherein said hydrogel has a water content between 37.5% and 75%. Schultz et al. teaches that the polymeric hydrogels contain a water content between 10-90%, which falls within the instantly claimed range. Furthermore as it is obvious to the skilled artisan that hydrogels contain water, it would have been within the purview of one of ordinary skill in the art to optimize the water content ratio as MPEP 2144.05 recites "where the general conditions in the claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Regarding claim 6 which recites the hydrogel of claim 1, wherein said drug is capable of being passively released into an ocular environment under ambient conditions, absent evidence of criticality, until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the polymer hydrogel which is instantly claimed.

Regarding claim 7 which recites the hydrogel of claim 1, wherein said drug is capable of being delivered to the posterior segment, and claim 8 which recites the drug is capable of being delivered to the macula or retina, absent evidence of criticality, until some material difference(s)

in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the polymer hydrogel which is instantly claimed.

Regarding claim 9 which recites the hydrogel of claim 1, wherein said drug is capable of being passively released into an ocular environment under existing conditions, absent evidence of criticality, until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the polymer hydrogel which is instantly claimed.

Claim 10 recites the hydrogel of claim 1, wherein said hydrogel is shaped as a contact lens. Schultz et al. teaches polymeric hydrogel contact lenses. (abstract)

Regarding claim 11 which recites the hydrogel is capable of correcting vision, and claims 12-13 which recite the vision range as +8 to -8 diopters, wherein the hydrogel has a base curve between 8 and 9, absent evidence of criticality, until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the polymer hydrogel which is instantly claimed.

Claim 14 recites the hydrogel of claim 1, wherein said hydrogel comprises an ionic polymer. Schultz et al. teaches that the polymer can be ionic. (paragraph 0031)

Claim 21 recites the hydrogel of claim 1, wherein the posterior segment disease is selected from the group consisting of diabetic retinopathy, macular degeneration, macular edema, and vascular retinopathy. This limitation further limits the intended use of the composition as recited in claim 1, and is therefore directed towards an indented use of the composition.

It would have been prima facie obvious to one of ordinary skill in the art to create a polymer hydrogel which comprises steroids identical to that which is instantly claimed because Shultz et al. suggests that it is well known in the art to incorporate steroids into polymer hydrogel contact lenses. Thus, it would have been obvious to the skilled artisan to incorporate steroids into the specific polymer hydrogels as taught by Schutlz.

Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. United States Patent Application 2002/0197300 and Schwartz, United States Patent 5,212,168 further in view of Miller et al. United States Patent Application 2004/0071761.

Schultz et al. teaches polymeric hydrogel contact lenses wherein the lenses gradually release medication. (abstract and paragraph 0014) Schultz et al. teaches a tetrapolymer hydrogel such as hydroxymethylmethacrylate, ethylene glycol, dimethylmethacrylate, and methacrylic acid. (paragraph 0020) The limitations wherein the hydrogel comprises a drug for the treatment of a posterior segment disease including diabetic retinopathy, macular degeneration, muscular edema, and vascular retinopathy, are interpreted by the Examiner as an intended use of the composition. MPEP 2111.02 recites "if a prior art structure is capable of performing the intended use as recited then it meets the claim." Schultz et al. expressly teaches the use of hydrogels to release drugs to the eye. Schultz further teaches that it is known to deliver such anti-glaucomatous medications in combination with corticosteroid medications and discloses U.S. Patent 5,212,168 which exemplifies that using polymeric hydrogel contact lenses to deliver anti-glaucomatous medications in combination with corticosteroid medications is well known in the

art. The corticosteroid medications of U.S. Patent 5,212,168 include that of prednisolone, prednisone, and hydrocortisone which can be delivered through a polymeric hydrogel. Regarding the limitations wherein the drug is used for the treatment of a posterior segment disease, the Examiner interprets said limitation as reciting an intended use. Regarding the limitation wherein the drug is capable of being passively released from the polymeric hydrogel while positioned on the eye in a therapeutically effective amount to ameliorate and/or stabilize neovascularization in the posterior segment; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner as a property and is directed toward the polymeric hydrogel which is instantly claimed.

Schultz et al. does not teach wherein the drug comprises angiogenesis inhibitor including VEGF antagonists.

Miller et al. teaches pharmaceutical compounds for the treatment of posterior retinal conditions of the eye. (paragraph 0028) The invention comprises a drug which is impregnated into a hydrogel. (paragraph 0073) It is well known in the art that hydrogels comprise water and polymers. Miller further teaches that drugs such as VEGF antagonists or steroids can be present as the drug. (paragraphs 0029 and 0059) Regarding the limitation "for the treatment of a posterior disease", the Examiner interprets said limitation as an intended use of the composition. Furthermore, Miller et al. teaches treating macular degeneration and disorders such as glioblastomas which affect all parts of the eye. (paragraph 0058) With regards to claim 25 which recites the hydrogel of claim 22 wherein the posterior segment disease is selected from the group consisting of diabetic retinopathy, macular degeneration, macular edema, and vascular

retinopathy. This limitation further limits the intended use of the composition as recited in claim 22, and is therefore directed towards an indented use of the composition.

It would have been prima facie obvious to one of ordinary skill in the art to create the polymer hydrogels of Schultz with drugs comprising VEG F antagonists or steroids. One would have been motivated to include VEGF antagonists or steroids into the hydrogel systems of Schultz because Schultz teach the delivery of drugs with such hydrogel systems, and Miller et al. exemplifies the use of VEGF antagonists and steroids with hydrogel systems for the treatment of ocular conditions.

Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. United States Patent Application 2002/0197300 and Schwartz, United States Patent 5,212,168 further in view of Sponsel et al. United States Patent Application 2004/0198829.

Schultz et al. teaches polymeric hydrogel contact lenses wherein the lenses gradually release medication. (abstract and paragraph 0014) The hydrogel is a tetrapolymer of hydroxymethylmethacrylate, ethylene glycol, dimethylmethacrylate, and methacrylic acid. Schultz et al. teaches a tetrapolymer hydrogel such as hydroxymethylmethacrylate, ethylene glycol, dimethylmethacrylate, and methacrylic acid. (paragraph 0020) The limitation wherein the hydrogel comprises a drug for the "treatment of a posterior segment disease is interpreted by the Examiner as an intended use of the composition. MPEP 2111.02 recites “if a prior art structure is capable of performing the intended use as recited then it meets the claim.” Schultz et al. expressly teaches the use of hydrogels to release drugs to the eye. Schultz further teaches that it

is known to deliver such anti-glaucomatous medications in combination with corticosteroid medications and discloses U.S. Patent 5,212,168 which exemplifies that using polymeric hydrogel contact lenses to deliver anti-glaucomatous medications in combination with corticosteroid medications is well known in the art. The corticosteroid medications of U.S. Patent 5,212,168 include that of prednisolone, prednisone, and hydrocortisone which can be delivered through a polymeric hydrogel. Regarding the limitations wherein the drug is used for the treatment of a posterior segment disease, the Examiner interprets said limitation as reciting an intended use. Regarding the limitation wherein the drug is capable of being passively released from the polymeric hydrogel while positioned on the eye in a therapeutically effective amount to ameliorate and/or stabilize neovascularization in the posterior segment; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner as a property and is directed toward the polymeric hydrogel which is instantly claimed. Regarding the limitation wherein the posterior segment disease includes, diabetic retinopathy,

Schultz et al. does not teach wherein the drug comprises angiogenesis inhibitor including VEGF antagonists.

Sponsel et al. teaches matrices of solid hydrophobic polymers wherein such matrices include hydrogels. (paragraph 0221) The therapeutic agents of the invention are delivered to the eye. (paragraph 0009) Sponsel et al. teaches the use of an angiogenesis inhibitor such as VEGF antagonists or angiostatins as the type of drugs that can be delivered the eye. (paragraph 0150 and 0172-0173) The diseases that can be treated with the invention of Sponsel can include that of neovascularization. (paragraph 0079) The limitations wherein the inhibitor is “capable of being

passively released from the polymeric hydrogel in a therapeutically effective amount to ameliorate and/or stabilize neovascularization in the posterior segment is interpreted by the Examiner as an intended use of the composition. Regarding claim 25, this limitation further limits the intended use of the composition as recited in claim 22, and is therefore directed towards an indented use of the composition.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to incorporate VEGF antagonists or angiostatins into the hydrogels of Schultz et al. This is because Sponsel et al. suggests the delivery of such hydrogel systems to the eye and teaches VEGF antagonists as a drug that can be included. There would have been a reasonable expectation of success because Schultz et al. teach the delivery of medicaments to the eye through the use of hydrogels.

Claim 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. United States Patent 6,410,045 and Schwartz, United States Patent 5,212,168.

Schultz et al. teaches polymeric hydrogel contact lenses wherein the lenses gradually release medication. (see claim 1 and column 2, lines 57-63) The hydrogel is a tetrapolymer of hydroxymethylmethacrylate, ethylene glycol, dimethylmethacrylate, and methacrylic acid. (see claim 4) The limitation wherein the hydrogel comprises a drug for the treatment of a posterior segment disease is interpreted by the Examiner as an intended use of the composition. Schultz et al. expressly teaches the use of hydrogels to release drugs to the eye. MPEP 2111.02 recites “if a

prior art structure is capable of performing the intended use as recited then it meets the claim." Schultz further teaches that it is known to deliver such anti-glaucomatous medications in combination with corticosteroid medications and discloses U.S. Patent 5,212,168 which exemplifies that using polymeric hydrogel contact lenses to deliver anti-glaucomatous medications in combination with corticosteroid medications is well known in the art. (column 4, lines 4-10) The corticosteroid medications of U.S. Patent 5,212,168 include that of prednisolone, prednisone, and hydrocortisone which can be delivered through a polymeric hydrogel. Regarding the limitations wherein the drug is used for the treatment of a posterior segment disease, the Examiner interprets said limitation as reciting an intended use. Regarding the limitation wherein the drug is capable of being passively released from the polymeric hydrogel while positioned on the eye in a therapeutically effective amount to ameliorate and/or stabilize neovascularization in the posterior segment; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner as a property and is directed toward the polymeric hydrogel which is instantly claimed.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to form polymeric hydrogels as taught by Schultz et al., wherein such hydrogels comprise steroids to ameliorate and/or stabilize neovascularization because Schultz et al. suggests that it is known in the art to incorporate corticosteroids into such hydrogels. There would have been a reasonable expectation of success as Schultz et al. teach the use of hydrogels to deliver drugs to the eye.

Claims 2-3, 6-14, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. United States Patent Application 6,410,045 and Schwartz, United States Patent 5,212,168

Claim 3 recites the polymeric hydrogel of claim 1, wherein the hydrogel has a water content of between 10% and 90%, and claim 3 recites the polymeric hydrogel of claim 2, wherein said hydrogel has a water content between 37.5% and 75%. Schultz et al. teaches that the polymeric hydrogels contain a water content between 38-60%, which falls within the instantly claimed range. (see claims 3 and 10) Furthermore as it is obvious to the skilled artisan that hydrogels contain water, it would have been within the purview of one of ordinary skill in the art to optimize the water content ratio as MPEP 2144.05 recites "where the general conditions in the claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Regarding claim 6 which recites the hydrogel of claim 1, wherein said drug is capable of being passively released into an ocular environment under ambient conditions, absent evidence of criticality, until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the polymer hydrogel which is instantly claimed.

Regarding claim 7 which recites the hydrogel of claim 1, wherein said drug is capable of being delivered to the posterior segment, and claim 8 which recites the drug is capable of being delivered to the macula or retina, absent evidence of criticality, until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the polymer hydrogel which is instantly claimed.

Regarding claim 9 which recites the hydrogel of claim 1, wherein said drug is capable of being passively released into an ocular environment under existing conditions, absent evidence of criticality, until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the polymer hydrogel which is instantly claimed.

Claim 10 recites the hydrogel of claim 1, wherein said hydrogel is shaped as a contact lens. Schultz et al. teaches polymeric hydrogel contact lenses. (abstract and claim 1)

Regarding claim 11 which recites the hydrogel is capable of correcting vision, and claims 12-13 which recite the vision range as +8 to -8 diopters, wherein the hydrogel has a base curve between 8 and 9, absent evidence of criticality, until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the polymer hydrogel which is instantly claimed.

Claim 14 recites the hydrogel of claim 1, wherein said hydrogel comprises an ionic polymer. Schultz et al. teaches that the polymer can be ionic. (see column 5, lines 51-54)

Claim 21 recites the hydrogel of claim 1, wherein the posterior segment disease is selected from the group consisting of diabetic retinopathy, macular degeneration, macular edema, and vascular retinopathy. This limitation further limits the intended use of the composition as recited in claim 1, and is therefore directed towards an indented use of the composition.

It would have been prima facie obvious to one of ordinary skill in the art to create a polymer hydrogel which comprises steroids identical to that which is instantly claimed because Shultz et al. suggests that it is well known in the art to incorporate steroids into polymer hydrogel

contact lenses. Thus, it would have been obvious to the skilled artisan to incorporate steroids into the specific polymer hydrogels as taught by Schutlz.

Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. United States 6,410,045 and Schwartz, United States Patent 5,212,168 further in view of Miller et al. United States Patent Application 2004/0071761.

Schultz et al. teaches polymeric hydrogel contact lenses wherein the lenses gradually release medication. (see claim 1 and column 2, lines 57-63) The hydrogel is a tetrapolymer of hydroxymethylmethacrylate, ethylene glycol, dimethylmethacrylate, and methacrylic acid. (see claim 4) The limitation wherein the hydrogel comprises a drug for the treatment of a posterior segment disease is interpreted by the Examiner as an intended use of the composition. Schultz et al. expressly teaches the use of hydrogels to release drugs to the eye. MPEP 2111.02 recites "if a prior art structure is capable of performing the intended use as recited then it meets the claim." Schultz further teaches that it is known to deliver such anti-glaucomatous medications in combination with corticosteroid medications and discloses U.S. Patent 5,212,168 which exemplifies that using polymeric hydrogel contact lenses to deliver anti-glaucomatous medications in combination with corticosteroid medications is well known in the art. (column 4, lines 4-10) The corticosteroid medications of U.S. Patent 5,212,168 include that of prednisolone, prednisone, and hydrocortisone which can be delivered through a polymeric hydrogel. Regarding the limitations wherein the drug is used for the treatment of a posterior segment disease, the

Examiner interprets said limitation as reciting an intended use. Regarding the limitation wherein the drug is capable of being passively released from the polymeric hydrogel while positioned on the eye in a therapeutically effective amount to ameliorate and/or stabilize neovascularization in the posterior segment; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner as a property and is directed toward the polymeric hydrogel which is instantly claimed.

Schultz et al. does not teach wherein the drug comprises angiogenesis inhibitor including VEGF antagonists.

Miller et al. teaches pharmaceutical compounds for the treatment of posterior retinal conditions of the eye. (paragraph 0028) The invention comprises a drug which is impregnated into a hydrogel. (paragraph 0073) It is well known in the art that hydrogels comprise water and polymers. Miller further teaches that drugs such as VEGF antagonists or steroids can be present as the drug. (paragraphs 0029 and 0059) Regarding the limitation "for the treatment of a posterior disease", the Examiner interprets said limitation as an intended use of the composition. Furthermore, Miller et al. teaches treating macular degeneration and disorders such as glioblastomas which affect all parts of the eye. (paragraph 0058) With regards to claim 25 which recites the hydrogel of claim 22 wherein the posterior segment disease is selected from the group consisting of diabetic retinopathy, macular degeneration, macular edema, and vascular retinopathy. This limitation further limits the intended use of the composition as recited in claim 22, and is therefore directed towards an indented use of the composition.

It would have been prima facie obvious to one of ordinary skill in the art to create the polymer hydrogels of Schultz with drugs comprising VEGF antagonists or steroids. One would

have been motivated to include VEGF antagonists or steroids into the hydrogel systems of Schultz because Schultz teach the delivery of drugs with such hydrogel systems, and Miller et al. exemplifies the use of VEGF antagonists and steroids with hydrogel systems for the treatment of ocular conditions.

Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. United States Patent 6,410,045 and Schwartz, United States Patent 5,212,168 further in view of Sponsel et al. United States Patent Application 2004/0198829.

Schultz et al. teaches polymeric hydrogel contact lenses wherein the lenses gradually release medication. (see claim 1 and column 2, lines 57-63) The hydrogel is a tetrapolymer of hydroxymethylmethacrylate, ethylene glycol, dimethylmethacrylate, and methacrylic acid. (see claim 4) The limitation wherein the hydrogel comprises a drug for the "treatment of a posterior segment disease is interpreted by the Examiner as an intended use of the composition. Schultz et al. expressly teaches the use of hydrogels to release drugs to the eye. MPEP 2111.02 recites "if a prior art structure is capable of performing the intended use as recited then it meets the claim." Schultz et al. expressly teaches the use of hydrogels to release drugs to the eye. Schultz further teaches that it is known to deliver such anti-glaucomatous medications in combination with corticosteroid medications and discloses U.S. Patent 5,212,168 which exemplifies that using polymeric hydrogel contact lenses to deliver anti-glaucomatous medications in combination with corticosteroid medications is well known in the art. (column 4, lines 4-10) The corticosteroid medications of U.S. Patent 5,212,168 include that of prednisolone, prednisone, and hydrocortisone which can be delivered through a polymeric hydrogel. Regarding the limitations

wherein the drug is used for the treatment of a posterior segment disease, the Examiner interprets said limitation as reciting an intended use. Regarding the limitation wherein the drug is capable of being passively released from the polymeric hydrogel while positioned on the eye in a therapeutically effective amount to ameliorate and/or stabilize neovascularization in the posterior segment; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner as a property and is directed toward the polymeric hydrogel which is instantly claimed.

Schultz et al. does not expressly teach wherein the drug comprises angiogenesis inhibitor including VEGF antagonists.

Sponsel et al. teaches matrices of solid hydrophobic polymers wherein such matrices include hydrogels. (paragraph 0221) The therapeutic agents of the invention are delivered to the eye. (paragraph 0009) Sponsel et al. teaches the use of an angiogenesis inhibitor such as VEGF antagonists as angiostatins as the type of drugs that can be delivered the eye. (paragraph 0150 and 0172-0173) The diseases that can be treated with the invention of Sponsel can include that of neovascularization. (paragraph 0079) The limitations wherein the inhibitor is "capable of being passively released from the polymeric hydrogel in a therapeutically effective amount to ameliorate and/or stabilize neovascularization in the posterior segment is interpreted by the Examiner as an intended use of the composition. Regarding claim 25, this limitation further limits the intended use of the composition as recited in claim 22, and is therefore directed towards an indented use of the composition.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to incorporate VEGF antagonists or angiostatins of Miller into the hydrogels

of Schultz et al. This is because Sponsel et al. suggests the delivery of such hydrogel systems to the eye and teaches VEGF antagonists as a drug that can be included. There would have been a reasonable expectation of success because Schultz et al. teach the delivery of medicaments to the eye through the use of hydrogels.

## RESPONSE TO REMARKS

Regarding the double patenting rejection, Applicants have acknowledged that they will file a terminal disclaimer over case 10/971,997 in either case upon allowance; therefore the rejection is maintained until further action.

Regarding the rejections over Schultz, (US Application 2002/0197300) Applicants argue that the current Application has a priority date of April 9,2003 and that the Declaration demonstrates that the subject matter of the '300 Application was not "by another," thus does not constitute prior art.

The Examiner respectfully submits that the current Application claims priority to provisional Application 60/461354. Provisional Application 60/461354 does not disclose the use of the specific tetrapolymer, therefore newly amended claims 1 and 22 do not receive priority back to 04/09/2003 but rather receives the date of 04/09/2004. Thus, Schultz remains available for use under 103(a) and contains a 102(b) date.

Regarding the rejections using Sponsel and Miller, Applicants argue that both Miller and Sponsel attempt to overcome the difficulties of drug delivery by using additional substances to increase the residence time of a drug or by reducing the amount of vascular clearance of the drug of interest and suggests a long felt need for a successful delivery mechanism for providing drugs

to the posterior segment. Neither reference suggests that the drugs may be delivered to the posterior segment through a hydrogel placed on the surface of the eye.

In response, the Examiner respectfully submits that even though Sponsel and Miller attempt to administer additional substances to increase the residence time of the drug or reduce the amount of vascular clearance of the drug of interest, the claims as they stand recite "comprising"' language, thus do not exclude Applicants invention from also delivering more than one compound within the hydrogel. With regards to delivery to the posterior segment, as the claims are currently directed towards a composition, MPEP 2111.02 recites "if a prior art structure is capable of performing the intended use as recited then it meets the claim." As the prior art teaches the structure of the hydrogel as currently claimed, it must be capable of performing the intended use for a composition.

Applicants have submitted a Declaration to illustrate one of skill in the art would not have expected posterior delivery of the drugs by the hydrogel along with two additional postdated references ( Amo and Myles) that illustrate that drops have poor bioavailability and are ineffective to treat diseases of the posterior segment.

In response the Examiner respectfully submits that while Amo and Myles discuss the difficulties of topical application of ophthalmic medicines is of limited benefit, it appears as though the difficulties associated with such topical medications are being administered through eye drops and other topical routes but not hydrogel type systems as Myles states that higher levels of drug reached the posterior segment through the use of a hydrogel, see page 2070 1st paragraph. Furthermore, for composition claims, MPEP 2111.02 recites "if a prior art structure is capable of performing the intended use as recited then it meets the claim." With regards to the

Declaration filed 03/30/2010, while it seems encouraging, it is not found persuasive. This is because as the prior art has the same structure as Applicant's claims and is being placed in the eye, it must be capable of performing the same delivery to the posterior segment as demonstrated above as per MPEP 2111.02. Applicants must provide data demonstrating unexpected results over the prior art hydrogels.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah Al-Awadi whose telephone number is (571) 270-7678. The examiner can normally be reached on 9:30 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bonnie Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/SARAH AL-AWADI/
Examiner, Art Unit 1619
/Shanon A. Foley/

Primary Examiner, Art Unit 1619